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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,338	08/07/2001	James Tobin	22058-516-DIV-CON	3551

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EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/924,338

Applicant(s)
James Tobin

Examiner
Prema Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 27, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 38-58 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 38-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group III (claim 18 and new claims 38-58) in Paper No. 8 (12/27/02) is acknowledged.

Claims 1-17, 19-37 have been canceled in Paper No. 8 (12/27/02).

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite the antibody being claimed.

3. The abstract of the disclosure is objected to because there is no mention in the instant abstract of the antibodies being claimed. Correction is required. See MPEP. § 608.01(b).

Claim rejections-35 USC § 112, first paragraph

4. Claims 18, 38-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody to a protein comprising the amino acid sequence set forth in SEQ ID NO:2, does not reasonably provide enablement for "all" antibodies to "all" human IL-11R proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification delimits the instant protein by reference to specific amino acid arrays as set forth in SEQ ID NO:2, however, in claims 18, 38-41, 51-58, the protein is defined by

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reference to the abbreviation IL-11R, wherein the abbreviation itself does not represent any distinguishing information concerning the disclosed protein. Moreover because the specification on page 3, lines 16-17, recites that “preferably” the protein has a biological activity of the IL-11R”, this abbreviation does not inherently correspond to a particular cytokine receptor, and claims that lack the recitation of structural properties encompass subject matter not supported by the instant specification. Molecules that are embraced by the claims are not adequately supported by the instant specification because the specification provides no guidance for how to make such molecules nor are examples provided as to how these molecules would be identified commensurate with the breadth of the claims. In the absence of an appropriate structural and/or functional reference, a person of ordinary skill in the art would be unable to make and use the antibody molecules embraced by the claims without undue experimentation because one could not distinguish the proteins envisaged by the specification and those which are unrelated.

With respect to claims 18, 38-41, 51-58, as recited, what is claimed in the instant invention broadly encompasses "all" antibodies to “all” IL-11R proteins, including variants thereof. While the specification discloses that the biological property which the IL-11R polypeptide is expected to exhibit (page 11, lines 1-18), the specification is non-enabling for the unlimited number of compositions comprising an antibody to a IL-11R protein, and which are encompassed by the scope of the claims. Claim 18 is a single means claim (M.P.E.P. 2164.08(a)). In In re Hyatt, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), the Courts have held that: “A single means claim, i.e. where a means recitation does not appear in combination with another

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recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph.” (A single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor). Since no material limitations for the antibody to the IL-11R protein have been recited in the claim, the claim encompasses every conceivable structure (means) for achieving the stated property (result), a fact situation comparable to Hyatt. The claimed invention encompasses compositions not envisioned or described in the specification, and neither does the specification disclose how these claimed compositions can be distinguished from each other. The specification only enables antibodies to a protein having the amino acid sequence shown in SEQ ID NO:2, the polypeptide having specific characteristics and properties (see page 11, lines 1-18). These properties may differ structurally, chemically and physically from other known proteins. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claims, in the instant application, the quantity of experimentation to determine which antibodies to other IL-11R proteins are encompassed by the scope of the claims is practically infinite and the guidance provided in the specification very little, thereby rendering the results of the assays taught in the specification unpredictable (see Example 5, page 31). Therefore, it would require undue experimentation to determine which antibodies to which IL-11R proteins, would be encompassed by the scope of the

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claims. The disclosure of a natural polypeptide of SEQ ID NO:2 is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass antibodies to every and all polypeptides, including mutants thereof. In In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), the Courts have held that:

"Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since some improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that the scope of the claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Furthermore, the amount of embodiments corresponding to the desirable compositions, may be innumerable, and the enabled embodiment amount to only one (SEQ ID NO:2). Therefore, there are substantial scientific reasons to doubt the scope of enablement, as set forth above. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe antibodies to any other polypeptide other than that whose amino acid sequence is shown in SEQ ID NO:2, and since it is deemed to constitute undue experimentation to determine all the others, the disclosure is not commensurate with the scope of the claims. Therefore, Applicants are not enabled for antibodies to a IL-11R protein having anything less than the amino acid sequence shown in SEQ ID NO:2. It is

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suggested that by employing conventional claim language, the claims be amended to include the SEQ ID NO of the specific polypeptide supported by the instant specification.

Claim rejections-35 USC § 112, second paragraph

5. Claims 18, 38-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is rejected as vague and indefinite for reciting "IL-11R" because the full meaning of the acronym "IL-11R" should be stated at its first use in any independent claim.

Claims 38-56 are rejected as vague and indefinite insofar as they depend on claim 18 for this limitation.

Conclusion

No claim is allowed.

Claims 11, 38-58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, set forth in this Office action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

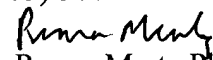
Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
January 22, 2003